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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/549,642	04/14/2000	Johan R. de Faire	314572-101F	9183

7590 01/02/2002

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EXAMINER

BRUMBACK, BRENDA G

ART UNIT PAPER NUMBER

1642

DATE MAILED: 01/02/2002 8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/549,642

Applicant(s)

DE FAIRE ET AL.

Examiner

Brenda G. Brumback

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 142-144 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 142-144 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/338,501.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. This action is responsive to the amendment filed 10/03/2001. New claims 143-144 were added. Claims 142-144 are pending and under examination.

Information Disclosure Statement

2. The Information Disclosure Statement filed 04/14/2000 is acknowledged. None of the cited documents were found in parent Application Serial No. 09/303,375, as was indicated on the Information Disclosure Statement; however, some of the cited documents were found in parent Application Serial No. 08/600,273. These documents have been considered, as is indicated on the attached Form PTO-1449. Documents which were not found or for which there was no English translation or statement of relevance were not considered. Additionally, the Dialog search documents were not considered, as no date was provided. Documents which were not considered are lined through on the Form PTO-1449. For consideration of those documents, applicant may wish to submit copies and a statement of relevance if the document is not in the English language.

Sequence Disclosures

3. Applicant's amendment deleting portions of the specification disclosing nucleotide and/or amino acid sequences is noted; however, the present application still fails to comply with the

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requirements of 37 CFR 1.821 through 1.825 for Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures because the originally filed Sequence Listing Paper Copy and CRF remain in the application. Additionally, there are embedded sequences which remain in the disclosure (see for example page 45, lines 29 and 31).

Applicant's request to use the Sequence Listing Paper Copy and CRF filed with parent application serial number 09/303,375 filed 04/14/00 in the present application is noted; however, that CRF is presently not in compliance.

Specification

4. The objection to the disclosure as containing amino acid sequences embedded within the text of the disclosure which are not referenced by sequence identifiers (SEQ ID NO:) is maintained for the reason set forth above.

Claim Rejections - 35 USC § 102/103

5. The rejection of claim 142 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hellgren et al. is maintained. Newly added claims 143-144 are also rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hellgren et al. for the reasons of record. Applicant's arguments have been fully considered but they are not persuasive.

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Applicant argues that the element of the present claims not expressly set forth in Hellgren et al. must necessarily flow from the disclosure of Hellgren and that this requirement is not met here. The examiner disagrees. The standard for inherency is that the prior art method, in its normal and usual operation, must necessarily perform the method claimed. The method disclosed by Hellgren et al. in which Hellgren et al. discloses contacting teeth with enzymes from krill in an amount effective for removing contaminants of biological origin and degradation products (see column 1, lines 10-41) necessarily performs the claimed method, *i.e.* it necessarily removes dental plaque from the teeth. Furthermore, removing biological contaminants and degradation products from teeth is equivalent to removing dental plaque from teeth because dental plaque is composed of biological contaminants and their degradation products. Applicant has provided no evidence to the contrary.

Applicant argues that in regard to the rejection under 103, that the disclosure of krill enzymes for use to debride wounds or clean textiles does not render the claims obvious and that effectiveness in the highly complex environment of dental plaque would not have been apparent to one of ordinary skill. The examiner disagrees. The disclosures in Hellgren et al. that krill enzymes are useful for enzymatic debridement, that krill enzymes can be used in the living body, and that krill enzymes effectively remove contaminants of biological origin and degradation products, such as pus, fibrin, coagulated blood, blood crusts, and necrotic tissue, from living and nonliving material, in combination with the specifically taught embodiment of cleaning teeth using krill enzymes, points directly to the claimed method of removing dental plaque from teeth.

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Applicant's arguments regarding the complexity of dental plaque and the failure of other enzymes to remove dental plaque are noted; however, these arguments do not appear to be germane to the present grounds of rejection because the patent referenced (6,159,447) does not teach away from the effectiveness of the krill enzymes disclosed by Hellgren et al. in removing contaminants and degradation products from teeth.

6. The rejection of claim 142 under 35 U.S.C. 103(a) as being unpatentable over Karistam in view of Ratcliff is maintained. Additionally, newly added claims 143-144 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karistam in view of Ratcliff for the reasons of record. Applicant's arguments have been fully considered but they are not persuasive for the following reasons.

Applicant argues that "The implication that because krill enzymes have at least some apparently appropriate classes of enzymes they would be effective in the real world, is mistaken". To reiterate the basis of the present obviousness rejection, Karistam teaches that krill enzymes effectively degrade proteins, glycoproteins, and glycosaminoglycans, including chondroitin sulfates. Ratcliff teaches that dental plaque is composed of proteins, glycoproteins, and glycosaminoglycans, including chondroitin sulfates. Ratcliff further teaches that degradation of proteins, glycoproteins, and glycosaminoglycans that include chondroitin sulfate retards dental plaque. The combination of the teachings found in the prior art would have led one of ordinary skill in the art at the time the invention was made directly to the claimed method. One of

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ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success in the “real world” based on these teachings.

NEW GROUNDS OF REJECTION

Specification

7. The amendment filed 10/03/2001 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The deletion of extensive portions of the disclosure introduces new matter. For example, deletion of the portions of the specification which describe the claimed enzymes from krill as isolated and purified and which describe the claimed enzymes as comprising a particular structure by amino acid sequence changes the scope of the enzymes encompassed within the present claims and constitutes new matter. Applicant is required to cancel the new matter in the reply to this Office action.

Claim Objections

8. Claim 144 is objected to because of the following informality. In line 2, “not” should be amended to -- no -- in order to correct the grammar.

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Claim Rejections - 35 USC § 112

9. Claims 142-144 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 143 and 144 recite “wherein the dental plaque is visually observable” and “wherein the contacting is conducted or repeated until dental plaque is not longer visually observable”. The newly added claims do not appear to enjoy support in the disclosure as originally filed. This matter might be resolved if applicant were to point out specifically where in the disclosure support for the newly recited material can be found.

Conclusion

10. No claims are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner Anthony Caputa whose telephone number is (703) 308-3995. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1642 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1642 FAX telephone number is (703)-305-3014. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

BB

December 21, 2001

Brenda Brumback
Brenda Brumback,
Patent Examiner